K090727

AUG 13 2009

Pre-market Notification for IMMTM Dental Irrigation Tubing Set

510(k) Summary

1. Submitter's Name:

INNOVATIVE MEDICAL MAUFACTURING COMPANY
107, 181 Lane, Sect. 1 Yong Jane Road
Chunan, Miaoli, 350 TAIWAN (ROC)

Contact: J. P. Lee, General Manager
Tel: +886-37-620236
Fax: +886-37-620239

2. Name of Device

Common/Usual Name:	Irrigation Tubing Set
Proprietary Name:	IMM™ Dental Irrigation Tubing Set
Classification Name:	Dental handpiece and accessories
Product Code:	EBW
Regulation Number:	21CFR872.4200

3. Predicate Device

Trade Name	510(k) Number	Decision Date
W&H Irrigation Tubing Set	K041124	06/07/2004

4. Device Description

The IMM™ Dental Irrigation Tubing Set is to be used for providing passage of irrigating fluid from a solution reservoir to a dental hand piece. The device consists of one or more inlet spikes, drip chamber, PVC plastic tubes, clamps, silicone tube, connectors, and end caps.

5. Indication for Use

The IMM™ Dental Irrigation Tubing Set is intended for providing passage of irrigating fluid from a solution reservoir to a dental handpiece.

6. Technological Characteristics

The IMM™ Dental Irrigation Tubing Set is a single use device, and is delivered sterile. The device can be readily connected to a dental handpiece in irrigation or fluid delivery.

7. Performance Summary

The functional and performance tests demonstrated that IMM™ Dental Irrigation Tubing Set meets specific requirements established in voluntary standards: ISO8536-4 and ISO8536-9. Biocompatibility test indicated that the device meets the requirements per ISO10993 for "limited exposure, tissue/bone/dentin contact, external communicating" devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Innovative Medical Manufacturing Company
C/O Joseph J. Chang, Ph.D., P.E.
Consultant
Innomedtech LLC
7128 Staffordshire Street
Houston, Texas 77030

AUG 13 2009

Re: K090727
Trade/Device Name: IMM™ Dental Irrigation Tubing Set
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: II
Product Code: EBW
Dated: July 21, 2009
Received: July 23, 2009

Dear Dr. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090727

510(k) Number (if known): K090727

Device Name: IMM™ Dental Irrigation Tubing Set

Indications for Use:

The IMM™ Dental Irrigation Tubing Set is intended for providing passage of irrigating fluid from a solution reservoir to a dental handpiece .

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulvey for M/SR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090727